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10/685,010	10/14/2003	Jack Engsborg	60019620-0228	4284

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EXAMINER

DOSTER GREENE, DINNATIA JO

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/685,010

Applicant(s)

ENGSTBERG ET AL.

Examiner

Dinnatia Doster-Greene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003 and 13 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-30 is/are allowed.
- 6) ☒ Claim(s) 1,2,8-14 and 17 is/are rejected.
- 7) ☒ Claim(s) 3-7 and 15-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detail Action.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 11, 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hepburn et al. (U.S. Patent No. 5,014,690).

First, the recitation “for determining a dorsiflexion angle of a surgical patient’s foot relative to the corresponding leg during tendon surgery” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Second, Hepburn discloses a leg member having a first support and a second support for engaging the lateral malleolus and medial malleolus (Col. 2, lines 16-18 and Figs. 1 and 4). Hepburn also discloses a foot member rotatably connected to the leg member for selectively rotating the foot member relative to the leg member about an axis defined by the first and second support of the leg

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member, the foot member having a metatarsal support adapted for engaging a predetermined point on at least one preselected metatarsal bone of the patient (Col. 2, lines 27-37 and Figs. 1, 2, 4 and 7).

Regarding claim 9, Hepburn discloses a shin support being sized and shaped for receiving a portion of the patient's shin (Col. 3, lines 14-18).

Regarding claim 11, the leg member of Hepburn discloses a strap as shown, for example, in Figs. 4, 8 and 9.

Regarding claim 12, Hepburn discloses a spring for biasing the second support toward the first support as discussed in col. 5, lines 11-15.

Regarding claim 17, Hepburn teaches that it is known to employ a stopping mechanism in order to limit the rotation of the foot member (Col. 6, lines 25-30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hepburn in view of Kaiser (U.S. Patent No. 5,297,540). Hepburn discloses the claimed invention as discussed above, with the exception of a gage connected between the leg member and the foot member for measuring an angle between the leg member and the foot member; and cushion for engaging the patient's shin. However, Hepburn does disclose that its device provides an adjustable locking means for selectively fixing the angular position of the foot support device relative to the lower struts so that the foot of the wearer is held in a predetermined position relative to the ankle of the wearer (Hepburn, col. 2, lines 32-36). Also in Hepburn, the tension exerted by spring 22 can be varied at any point of joint range of motion from 60° flexion to 0° flexion of the ankle joint. The spring mechanism of Hepburn can be calibrated to exert the range of tension by providing spring-abutting member 29 with a poundage indicator line 35 and a calibration scale 37 (Hepburn, col. 5, lines 31-39). In addition, Kaiser, which also discloses an orthopedic device comprising a rotating foot member, teaches that it is known in the art to incorporate a gage 164 capable of measuring the angle between the leg member and the foot member (Kaiser, col. 6, line 62- col. 7, line 2 and col. 9, lines 23-27). Thus, it would have been obvious to one skilled in the art to include the gage of Kaiser for the purpose of

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providing the user with a means of more accurately adjusting the angle of flexion of the ankle.

Furthermore, Kaiser discloses in Fig.1 that a cushion material may be used in a shin support 58. Thus, it would have been obvious to modify the shin support of Hepburn to include the cushiony shin support of Kaiser for the purpose of providing comfort to the patient.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hepburn in view of Cronk (U.S. Patent No. 4,572,170) or Horne (U.S. Patent No. 3,779,654). Hepburn discloses the claimed invention as discussed above, with the exception of a clevis joint connecting the leg member and the foot member. However, Cronk or Horne teaches that it is well known in the orthopedic field to include a clevis joint to serve as a pivot joint. Thus, it would have been obvious to one skilled in the art to substitute the socket 9 of Hepburn with the clevis joint of Cronk or Horne for the purpose of providing a pivot joint which is capable of simulation motion of a natural slide and hinge joint of the body such as those at the knee, elbow or ankle.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hepburn in view of Sherman (U.S. Patent No. 2,428,342). Hepburn discloses the claimed invention as discussed above, with the exception of the metatarsal support having a recessing for receiving one of a first metatarsal head and a fifth metatarsal head of the patient therein. Sherman, which also relates to an orthopedic device, discloses a foot corrective device having a recess which is capable of receiving one of a first metatarsal head and

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a fifth metatarsal head of the patient. Although Sherman states in col. 3, lines 69-75 that the anterior border 50 of the outer side 31 at its farthest point forward reaches to a point immediately behind the head of the fifth metatarsal bone, it is obvious that the foot corrective device of Sherman is capable of extending to and receiving at least one of the first metatarsal head and the fifth metatarsal head of the patient. Thus, it would have been obvious to one skilled in the art to substitute the foot corrective device of Sherman with the footplate of Hepburn for the purpose of providing a device capable of treating a weak or deformed foot.

Allowable Subject Matter

Claims 3-7 and 15-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 18-30 are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Line (U.S. Patent No. 1,607,834); Storer (U.S. Patent No. 3,643,659); Burris et al (U.S. Patent No. 3,880,417); Johnston (U.S. Patent No. 2,267,924); Patchel et al (U.S. Patent No. 5,358,469); Melhart (U.S. Patent No. 4,323,080); Jungmann (U.S. Patent No. 2,099,401); Malewicz (U.S. Patent No. 5,571,078); and Stetman et al. (U.S. Patent No. 5,176,623).

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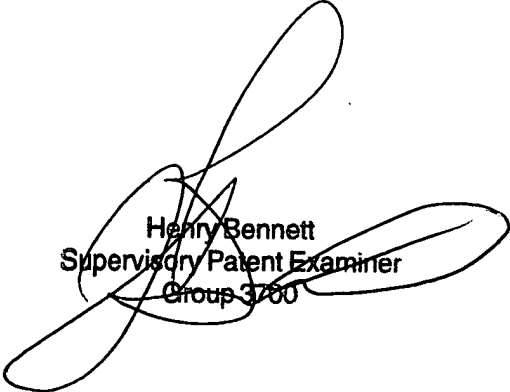
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dinnatia Doster-Greene whose telephone number is 571-272-7143. The examiner can normally be reached on 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-272-7143.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ddg



Henry Bennett
Supervisory Patent Examiner
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